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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,293	12/20/2006	John Babis	068911.0126	9021
23630	7590	02/10/2009	EXAMINER	
MCDERMOTT WILL & EMERY LLP			MELLER, MICHAEL V	
28 STATE STREET				
BOSTON, MA 02109-1775			ART UNIT	PAPER NUMBER
			1655	
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			02/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/557,293	BABISH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 January 2009.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-41 is/are pending in the application.
- 4a) Of the above claim(s) 17-36 and 39-41 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 3-16, 37, 38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, tetrahydroisohumulone and ibuprofen in the reply filed on 5/12/2008 is acknowledged. The traversal is on the ground(s) that there are only 9 compounds claimed of the reduced isoalpha acids and that NSAIDs can easily be searched with the 9 reduced isoalpha acids. This is not found persuasive because all of the claims are not limited to the 9 reduced isoalpha acids that applicant alleges further NSAIDs encompass many more hundreds of compounds which fall outside of the claimed species found in claims 11 and 12. The requirement to the source is withdrawn.

Claims 17-36, 39-41 are withdrawn from further consideration as being drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 4-7 of US Patent Application Number 10789814. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

4. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 29-34 of US Patent Application No. 11344552. This is a

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provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

5. Claims 1, 3-16, 37, 38 are rejected on the ground of nonstatutory double patenting over claims 1-11 of U. S. Patent No. 7,195, 785 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

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6. Claims 1, 3-16, 37, 38 are rejected on the ground of nonstatutory double patenting over claims 1-8 of U. S. Patent No. 7,270, 835 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

7. Claims 1, 3-16, 37, 38 are rejected on the ground of nonstatutory double patenting over claims 1-3 of U. S. Patent No. 7,279, 185 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

8. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 91-97, 99-102, 105-109 of US Patent Application Number

11344555. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

9. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 2-15 of US Patent Application Number 11344554. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

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10. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 110-134 of US Patent Application Number 11344556.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

11. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 51, 116-131 of US Patent Application Number 11344557. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application,

thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

12. Claims 1, 3-16, 37, 38 are provisionally rejected on the ground of nonstatutory double patenting over claims 20-28 of US Patent Application Number 11344559. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: the hops extracts are noted as being effective in treating inflammatory conditions as NAIDs do in the application, thus it would have been obvious to add the hops extracts to the NAIDs in an effort to achieve combined results of two effective anti-inflammatories.

If applicant is aware of any remaining potential Obviousness type double patenting issues applicant is hereby required to state what the applications/patents are and the claims that they conflict with. Applicant will have to file terminal disclaimers to obviate these issues as they will have to for the above rejections.

***Claim Rejections - 35 USC § 112***

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1, 3-5, 7-10, 13-15, 37, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a composition comprising a reduced isoalpha acid, dihydro isoalpha acid, tetra hydro isoalpha acid or hexahydro isoalpha acid along with a NSAID (non-aspirin, non-steroidal anti-inflammatory). Thus, the claims are drawn to a genus of compounds which are not completely quantifiable.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims is drawn to

a composition comprising a reduced isoalpha acid, dihydroisoalpha acid, tetra hydro isoalpha acid or hexahydroisoalpha acid along with a NSAID. The specification appears to teach that specific reduced isoalpha acids such as tetrahydroisohumulones are known and certain NSAIDs such as ibuprofen are known but not any and all reduced isoalpha acids and NSAIDs. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompassed by the claims as noted.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of inhibitors, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v.Revel, 25USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18USPQ2d 1016.

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One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the compounds of claim 6 have written description and the NSAIDs of claims 11 and 12, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/  
Primary Examiner, Art Unit 1655